In response to the Restriction Requirement and the Requirement for an Election of Species, Applicant elects the invention of Group I and the paste formulation of claim 45 as the elected composition COX-2 inhibitors as the therapeutic agent and oral administration as the dosage form. Claims 1, 4, 5, 6, 7, 11, 12, 13, 45, and 46 read upon the elected formulation. Applicant traverses the Restriction Requirement and request its modification or withdrawal. Likewise, Applicant traverses this requirement for an election of species if this means that the Examiner will not extend the search if the elected composition is found allowable. For example, it is not seen where the presence of a surfactant or a preservative would constitute an undue burden. It is requested that the Examiner indicates on the record how the requirement for an election of species; i.e., as a searching aid or as a restriction requirement.

Applicant respectfully traverses this Requirement if it is used by the Examiner as a restriction requirement. Applicant urges that the Restriction is improper as it does not establish that searching all the species constitutes an undue burden to the Office and because it is contrary to public policy. Accordingly, modification or withdrawal of this Requirement is respectfully requested.

With regard to the restriction between Group I and Group VIV, Applicant requests further clarification or literature, which supports the Examiner's position. The Office Action argues that these inventions are distinct because the product can be made in a materially different process such as genetic engineering. For the reasons provided below, Applicant urges that this statement is not credible on its face.

The MPEP lists two criteria for a proper Restriction Requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The

MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions." *Id.*

The inventive compositions are directed to novel paste formulations comprising an effective amount of a therapeutic agent, fumed silica, a viscosity modifier, a carrier and, optionally, other formulation aids such as absorbents, colorants, stabilizers, surfactants or preservatives. The inventive process according to claim 44 provides for an improved process to make the inventive paste products. Applicant is not aware of any bacteria or virus that will produce a paste formulation that comprises a therapeutic agent, fumed silica, a viscosity modifier, a colorant and a carrier. To the best of his knowledge, fumed silica colorants and viscosity modifiers are not produced by genetic engineering, let alone a bacteria or a virus that will produce the combination of all four components. Moreover, Applicant urges that searching both groups would not constitute an undue burden as a search of the process includes a search of the products obtained by that process. Accordingly, it is urged that the Requirement does not meet its burden and reconsideration and withdrawal of this requirement between these groups is requested.

Moreover, Applicant urges that requiring restriction between the formulations and the various uses is also improper as the Office Action does not establish searching the therapeutic agent with its biological method of use is improper. Accordingly, reconsideration and modification or withdrawal of this requirement, at least with respect to the therapeutic agents actually searched in accordance with the election of species is requested; i.e., claims 28 to 31 should be rejoined with the elected invention as these uses are associated with COX-2 inhibitors.

The methods of use are those associated with particular classes of therapeutic agents. Accordingly, a search of the therapeutic agent would overlap with a biological method of using the agent. This would occur even in a literature search for a particular therapeutic agent. Accordingly, it is urged that the Requirement has not established that searching all the groups, while distinct, constitutes an undue burden and reconsideration and modification or withdrawal of this requirement is requested.

Further, it is respectfully urged that restricting the claims in the manner suggested in the Requirement constitutes an undue burden to Applicant as well as the public. Hence, it is against public policy. If followed, the Requirement would require Applicant to file numerous patent applications, depending upon how the Examiner uses the election of species. The cost of prosecuting and maintaining so many patents is unreasonable in view of the fact that Applicant cannot ascertain at this point how many inventions the Patent Office considers to be present in the present claims. Further, under GATT, the period of exclusivity for any patents which issue from the divisional application is greatly reduced. Applicant cannot take any action to reduce this effect since it is not known how the Examiner will use the requirement for an election of species. Similarly, the public is inconvenienced as they will not know whether or not Applicant will file divisional applications to the remaining subject matter. Accordingly, the public will not know if they can practice the remaining invention without infringing future patent applications.

Finally, the Examiner queries as to why the application includes Appendix I. The Examiner's attention is respectfully directed to page 2, lines 4 to 10 of the specification which states:

> Reference is made to the following U.S. applications: Ser. No. 09/346,905, filed July 2, 1999, now pending; Ser. No. 09/112,690, filed July 9, 1999, now allowed; and Ser. No. 09/15,277, filed September 14, 1998, now pending, entitled **LONG ACTING**

> **INJECTIBLE FORMULATIONS CONTAINING HYDROGENATED CASTOR OIL**. Reference is also made to EP 99 402 482.6, filed on October 8, 1999, appended hereto as part of the application as Appendix I. The disclosure of these [sic] patent application as well as the references cited therein and the references cited herein are expressly incorporated by reference.

(emphasis added).

Accordingly, in view of the foregoing, reconsideration and modification of this Restriction Requirement is requested and an early action on the merits is earnestly solicited.

Respectfully submitted,

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